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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,834	09/25/2006	Satoshi Amano	2756IU	9819
20529 7590 12/30/2008				
THE NATH LAW GROUP				
112 South West Street				
Alexandria, VA 22314				
EXAMINER				
GRANO, ERNESTO ARTURIO				
ART UNIT		PAPER NUMBER		
3728				
MAIL DATE		DELIVERY MODE		
12/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/587,834

**Applicant(s)**

AMANO ET AL.

**Examiner**

ERNESTO A. GRANO

**Art Unit**

3728

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

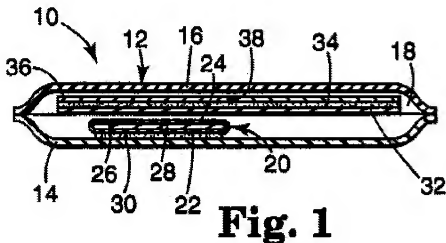
1. Receipt is acknowledged of Applicant's amendment filed on 09/05/2008.
  - Claim 1 was amended
  - Claim 7 was canceled
  - Claims 1-6 and 8-9 are presented for examination.
  - This action is **Non-Final**

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US Patent 5,698,217) in view of Klokkers et al (PG PUB US 2004/0086552) in view of Kanios et al. (US Patent 6,905,016) in view of Higo et al. (US 5,866,157) in further view of Asmussen et al. (US 6267,982).



**Fig. 1**

In re claim 1, with reference to figure 1, Wilking ('217) discloses a patch-containing packaging pouch (10) comprising: a packaging pouch (12); and a patch (38), housed within the packaging pouch (12), in which a pressure-sensitive adhesive layer (34) is formed on one side of a support, wherein the pressure-sensitive adhesive layer (34) is formed of a pressure-sensitive adhesive composition containing a pressure-sensitive adhesive and a dissolved drug.

However, Wilking ('217) fails to disclose a pressure-sensitive adhesive comprising at least one compound selected from the group consisting of a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer, and bisoprolol or pharmaceutically acceptable salt thereof, wherein the content of bisoprolol is 1 to 50% by mass in the pressure-sensitive adhesive composition, and relative humidity inside the-packaging pouch at 25°C is maintained at 25% or less.

Klokkers et al ('552) teaches a transdermal therapeutic system comprising a surface layer which is impervious with respect to an active ingredient, bisoprolol. (see page 3, paragraph 76)

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the patch (38) of Wilking ('217) with bisoprolol as its

dissolved drug as taught by Klokckers et al ('552) in order to create a patch for treating people with a cardiovascular disease.

Kanios et al. ('016) teaches a product packaging system to prevent or control degradation reactions that can result from certain packaging materials and moisture contamination, which includes a pressure-sensitive adhesive made of an acrylic polymer. (see col. 7, lines 23-36)

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pressure-sensitive adhesive of Wilking ('217) and Klokckers et al ('552) as applied above, to include an acrylic polymer pressure-sensitive adhesive as taught by Kanios et al. ('016) in order to use an adhesive that will not have a reaction with certain drugs.

Higo et al. ('157) teaches organic acids and water-soluble salts which can be formulated in the amounts of 0.01 to 10% (w/w) based on the total amount of composition of the adhesive layer. (see column 3, lines 9-54)

Thus, It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pressure-sensitive adhesive of Wilking ('217), Klokckers et al ('552), and Kanios et al. ('016) as applied above, with the drug content of 1 to 50% by mass as taught by Higo et al. ('157) in order to minimize skin irritation.

Asmussen et al. ('982) teaches a packaging pouch with a skin-adhering drug patch, which the air enclosed in the packaging pouch is adjusted to relative air humidity between 5% and bellow 0.5%. (see abstract and column 4, lines 2-13)

Thus, It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the packaging pouch of Wilking ('217), Klokckers et al

('552), Kanios et al. ('016), and Higo et al. ('157) as applied above, with relative air humidity between 5% and below 0.5% as taught by Asmussen et al. ('982) in order to keep the drug dissolved.

Furthermore, It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In re claim 2, Asmussen et al. ('982) discloses the relative humidity is maintained at 10% or less. (see column 4, lines 2-13)

In re claim 3, with reference to figure 1, Wilking ('217) discloses a desiccant (20) that is housed within the packaging pouch (12).

In re claim 4, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a substance which physically adsorbs moisture. (see col. 3, lines 23-44)

In re claim 5, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a porous substance. (see col. 4, lines 1-14)

In re claim 6, with reference to figure 1, Wilking ('217) discloses a desiccant (20) is a desiccant (22 and 24) formed of a porous substance formed of at least one type of material selected from the group comprising a metal oxide, zeolite and a clay mineral. (see col. 4, lines 1-54)

In re claim 8, with reference to figure 1, Wilking ('217) discloses the packaging pouch (10) has a blocking layer (14) that blocks penetration of moisture. (see col. 6, lines 44-47)

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US Patent 5,698,217), Klokckers et al (PG PUB US 2004/0086552), Kanios et al. (US Patent 6,905,016), Higo et al. (US 5,866,157), and Asmussen et al. (US 6267,982) as applied to claim 1 above, and in further view of Takayuki et al. (Japanese Patent 61-73547).

In re claim 9, with reference to figure 1, Wilking ('217), Klokckers et al ('552), Kanios et al. ('016), Higo et al. ('157), and Asmussen et al. ('982) as applied to claim 1 above, discloses the claimed invention except for the packaging pouch having a layer formed from polyacrylonitrile on the innermost side.

Takayuki et al. ('547) teaches an anti-inflammatory, analgesic drug packaging body formed by affixing a peel-off film configured from a polyacrylonitrile-based resin on the drug coated surface of a film-like anti-inflammatory, analgesic drug, and packaging and hermetically-sealing the same in a bag having an innermost layer of polyacrylonitrile-based resin which forms the innermost layer of the bag.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the innermost layer of the packaging pouch (10) of Wilking ('217), Klokckers et al ('552), Higo et al. ('157), and Asmussen et al. ('982) as applied to claim 1 above, to include a polyacrylonitrile-based resin as its inner most layer as taught by Takayuki et al. ('547) in order to keep moisture to a minimum within the package.

#### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-6 and 8-9 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNESTO A. GRANO whose telephone number is (571)270-3927. The examiner can normally be reached on 7:00am - 4:00pm Mon.-Thur..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bryon P. Gehman/  
Primary Examiner, Art Unit 3728

/Ernesto A Grano/  
Examiner  
Art Unit 3728

EAG